

**REMARKS**

Claims 2 and 8-19 are pending in the application. With the entry of this amendment, claim 2 of Group I is withdrawn, claims 8-12 of Group II are withdrawn, and claim 21 is added. Thus, claims 13-19 and 21 are currently under examination.

Restriction/Election Requirement

The Examiner restricted the invention to one of three different groups stating the combination (i.e. the treatment of Alzheimer's disease using an agent (e.g. thiazolidinedione and group II) does not require the particulars of group I (i.e. chromium) as evidenced by the instant claims. See Office Action of August 30, 2004, at pages 2-3. Applicants elect Group III, claims 13-19, allegedly drawn to "a method of treating Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of an agent which increases the insulin sensitivity of the human and restricting the metabolizable carbohydrates in the diet of the human, classified 514 or 424" with traverse.

In traversing, the Applicants submit that the restriction requirement is improper, for failing to set forth the two criteria mandated under the Manual of Patent Examining Procedure ("MPEP") §803 for a proper restriction requirement:

“(A) The inventions must be independent (see MPEP §802.01, §806.04, §808.01) or distinct as claimed (see MPEP §806.05 - §806.05(i)); **and**  
(B) **There must be a serious burden on the examiner** if restriction is required (see MPEP §803.02, §806.04(a)-§806.04(i), §808.01(a), and §808.02).”  
(Emphasis added.)

No such serious burden has been alleged in the Office action, and it is Applicants' position that no such serious burden exists. Moreover, the Office has not provided any reasoning as to why the inventions of Group III and Group II are patentably distinct. Applicants respectfully assert that the combination of Group III (i.e., the treatment of Alzheimer's disease using an agent **and** restricting the metabolizable carbohydrates in the diet) necessarily requires

the particulars of the subcombination of Group II (i.e., the treatment of Alzheimer's disease by restricting the metabolizable carbohydrates in the diet). As such, Applicants respectfully request that at least Groups II and III be combined. Applicants respectfully request that the required finding be made of record, or that the restriction requirement be withdrawn.

Further, the Examiner requires under U.S.C. 121, an election of species within the claims of Group III. In order to be fully responsive and without acquiescing to the Examiner's assertion, the Applicants elect the method of claim 13 wherein said agent is a thiazolidinedione, with traverse. Claims 13-19 and 21 read on this species.

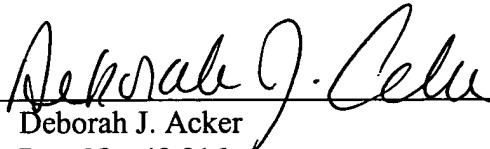
Finally, in traversing, the Applicants submit that the required species election between chromium, insulin-like growth factor, a dopamine agonist or a thiazolidinedione is contrary to definition of species in the Manual of Patenting Examining Procedure (MPEP). *See e.g.*, MPEP §§ 806.04(e), (d). Nonetheless, simply to advance prosecution and not in any acquiescence to the characterization of the claims, as set forth above, Applicants have elected "a thiazolidinedione." Applicants reserve the right to claim additional species upon allowance of a generic claim.

If there are any further fees due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 29, 2004

By:   
Deborah J. Acker  
Reg. No. 48,916